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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,092	11/16/2001	David G. Charne	1271	7842
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PIONEER HI-BRED INTERNATIONAL INC. 7100 N.W. 62ND AVENUE P.O. BOX 1000 JOHNSTON, IA 50131				
			EXAMINER KRUSE, DAVID H	
			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,092

Applicant(s)

CHARNE ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-11,13-19,21-27,29-34 and 56-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13,23,56,58,60 and 61 is/are rejected.
- 7) ☒ Claim(s) 1-5,7-11,14-19,21,22,24-27,29-33,57 and 59 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. SAME.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed 21 June 2004.
2. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments to the claims.
3. The Objection to specification as directed to incorporation by reference to a foreign application is withdrawn in view of Applicant's amendment to the specification.
4. The rejection of the claims for lack of enablement under 35 USC 112, first paragraph, because of the need for a deposit of biological material is withdrawn in view of Applicant's statement on page 12 of the Remarks. The specification has been objected to in view of the amendment to page 18 because it appears contradictory to said statement in the Remarks (see below). The Examiner has discussed this issue with Applicant's attorney Marianne Michel (see attached interview summary).
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

6. Receipt is acknowledged of papers submitted on 21 June 2004 under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file.

Specification

7. The disclosure is objected to because of the following informalities: The Amendment to the specification on page 18, line 10, filed 21 June 2004 is objected to because it is unclear what the amendment is stating. Lines 3-5 state that a deposit will

be maintained under the terms of the Budapest Treaty, but does not state where the deposit will be maintain. In addition, the statement at lines 5-7 appears to contradict the statement at lines 3-5, 37 CFR §§ 1.801-1.809 are directed to the conditions under which a deposit are made, not their requirement for patentability, such a requirement would be under 35 USC § 112, first paragraph, for enablement of the claims.

Clarification is required.

Claim Objections

8. Claim 34 is objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 34 no longer further limits claim 29 and should be cancelled.

9. Claims 1, 7, 14 and 29 are objected to because of the following informalities: The phrase "plant is designated variety", at line 3 of claim 1 for example, should read -- plant is variety -- for consistence with claim 22. Appropriate correction is required.

10. Claim 15 is objected to because of the following informalities: The listing of species should be recited in the singular, -- a tissue, pollen, an ovule, a root, a leaf, a seed and a microspore --. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. Claims 13, 23, 60 and 61 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite because it is unclear if Applicant is claiming somoclonal variants of variety NS3801 or a plant -- having all of the morphological and physiological characteristics of *Brassica napus* variety NS3801 --. Hence, the metes and bounds of the claimed invention are unclear.

Claim 23 is indefinite because it is unclear what is used in the "breeding program", and how specifically the "breeding program" is to be practiced, hence the metes and bounds of the claim are unclear.

At claim 60, lines 1-2, the limitation "wherein said progeny plant cell" lacks proper antecedent basis within the claim. Claim 61 is also indefinite because it does not obviate the indefiniteness of claim 60.

12. Claims 13 and 23 remain rejected and claims 56, 58 and 60 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 19 December 2003. Applicant's arguments filed 21 June 2004 have been fully considered but they are not persuasive.

Claim 13 lacks adequate written description because it reads on somoclonal variants produced in a tissue culture, examples of which Applicant does not describe in the instant specification.

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Claim 23 lacks adequate written description because it is directed to a method of plant breeding using progeny of the described *B. napus* variety NS3801 that have not been adequately described. A method is not described if products used in the method are not described. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4.

New claims 56, 58 and 60 are directed to progeny plants, seeds and cells of *B. napus* variety NS3801 produced from an unspecified number of crosses, wherein Applicant only adequately describes *B. napus* variety NS3801 in the instant application. In addition, it is unclear from where the traits of Early Napus and resistance to at least one AHAS-inhibitor herbicide are inherited. The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern, US Patent 5,850,009, column 4, lines 41-46). Hence, one cannot adequately describe progeny plants by only describing one parental variety.

13. Claims 13 and 23 remain rejected and claims 56, 58 and 60 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 19 December 2003.

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Applicant's arguments filed 21 June 2004 have been fully considered but they are not persuasive.

Claim 13 has been amended from a method claim to a product claim. Claim 13 lacks adequate enablement because it reads on somoclonal variants not taught by Applicant in the instant specification. Given the unpredictability of somoclonal variant produced from tissue cultures it would have required undue trial and error experimentation by one of skill in the art to identify and use such variants as broadly claimed. Amending the claim as suggested supra would obviate this rejection.

Claim 23 lacks adequate enablement because it reads on the use of progeny plants of the exemplified *B. napus* variety NS3801. The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern, US Patent 5,850,009, column 4, lines 41-46). The nature of the art at the time of Applicant's invention was such that one of skill in the art could not reasonably predict what the product of a cross between two inbred parental plants would be without a reduction to practice. The art teaches that "Even if an inbred in hybrid combination has excellent yield (a desired characteristic), it may not be useful because it fails to have acceptable parental traits such as seed yield, seed size, pollen production, good silks, plant height, etc." (Carlone, U.S. Patent 5,763,755, column 2, lines 11-14). The art teaches that based on the number of segregating genes, the frequency of occurrence of

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any individual with a specific genotype is less than 1 in 10,000 and that even if the entire genotype of the parents has been characterized and the desired phenotype is known, only a few if any individuals having the desired genotype may be found in a large F_2 or S_0 population and that typically the genotype of neither the parents nor the desired genotype is known in detail (see Segebart, U.S. Patent 5,304,719, in particular the paragraph spanning columns 2-3). The art also teaches that the number of genes affecting the trait of primary economic importance in maize, grain yield, has been estimated to be in the range of 10-1000 and that inbred lines which are used as parents for breeding crosses differ in the number and combination of these genes (Segebart, U.S. Patent 5,367,109, column 2, lines 60-64). Segebart ('109) also teaches that one of the largest plant breeding programs in the world does not have a sufficiently large breeding population to be able to rely upon "playing the numbers" to obtain successful research results and that plant breeders use their skills, experience and intuitive ability to select inbreds having the necessary qualities (column 4, 1st and 2nd paragraphs). Hence, given the fact that one of skill in the art cannot reasonably predict the number of genes that affect the trait of grain yield of the parental inbred lines of a inbred maize plant, it is unclear how one of skill in the art could reasonably predict how to make and use the claimed maize plants and methods of making a maize plant using a second or filial non-exemplified maize plant produced from Applicant's exemplified inbred maize plant. Applicant's claim is directed to breeding of *Brassica* using a *B. napus* variety, which is an amphidiploid species, and thus would be even more complex due to the

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presence of two genomes, which genomes generally segregating independently of each other.

Claims 56, 58 and 60 lack adequate enablement because they are directed to progeny plants, parts and seeds produced from the exemplified variety NS3801 from an unspecified number of crosses. In addition, it is unclear from where the traits of Early Napus and resistance to at least one AHAS-inhibitor herbicide are inherited. The instant claims lack adequate enablement for the reasons given above. It would only be evident to one of skill in the art that the traits of Early Napus and resistance to at least one AHAS-inhibitor herbicide would be inherited from variety NS3801 in the F1 progeny.

Allowable Subject Matter

14. Claims 57 and 59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Claims 1-5, 7-11, 14-19, 21, 22, 24-27 and 29-33 would be allowable if the objection to claims 1, 7, 14 and 29 is overcome by amendment.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within


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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Claims 13, 23, 56, 58 60 and 61 are rejected.
18. Claims 1-5, 7-11, 14-19, 21, 22, 24-27 and 29-33 are objected to.
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.


DAVID H. KRUSE, PH.D.
PATENT EXAMINER

David H. Kruse, Ph.D.
28 September 2004

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20. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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